

Middlesex University Research Repository

An open access repository of

Middlesex University research

<http://eprints.mdx.ac.uk>

Staunton, Ciara ORCID logoORCID: <https://orcid.org/0000-0002-3185-440X> (2018) The regulation of stem cell research in Ireland: from the Commission on Assisted Human Reproduction to the Assisted Human Reproduction Bill 2017. *Medical Law International*, 18 (1) . pp. 35-58. ISSN 0968-5332 [Article] (doi:10.1177/0968533218764543)

Final accepted version (with author's formatting)

This version is available at: <https://eprints.mdx.ac.uk/24338/>

Copyright:

Middlesex University Research Repository makes the University's research available electronically.

Copyright and moral rights to this work are retained by the author and/or other copyright owners unless otherwise stated. The work is supplied on the understanding that any use for commercial gain is strictly forbidden. A copy may be downloaded for personal, non-commercial, research or study without prior permission and without charge.

Works, including theses and research projects, may not be reproduced in any format or medium, or extensive quotations taken from them, or their content changed in any way, without first obtaining permission in writing from the copyright holder(s). They may not be sold or exploited commercially in any format or medium without the prior written permission of the copyright holder(s).

Full bibliographic details must be given when referring to, or quoting from full items including the author's name, the title of the work, publication details where relevant (place, publisher, date), pagination, and for theses or dissertations the awarding institution, the degree type awarded, and the date of the award.

If you believe that any material held in the repository infringes copyright law, please contact the Repository Team at Middlesex University via the following email address:

eprints@mdx.ac.uk

The item will be removed from the repository while any claim is being investigated.

See also repository copyright: re-use policy: <http://eprints.mdx.ac.uk/policies.html#copy>

The Regulation of Stem Cell Research in Ireland: From the Commission on Assisted Human Reproduction to the Assisted Human Reproduction Bill 2017

Abstract

In 2005 Ireland's Commission on Assisted Reproduction (CAHR) published a comprehensive report on the regulation of assisted reproduction and associated technologies. Yet since that Report, successive Irish governments have failed to bring forth any legislation on this matter. This legislative inaction has resulted in a situation whereby the embryo in vivo has the right to life under the Irish Constitution, but embryos in vitro have no protection in law. Irish policy makers have also endorsed and funded embryonic stem cell research (ESCR) at a European level, but continues to prevent researchers in Ireland from accessing any public funds for this research. The publication in October 2017 of the General Scheme of the Assisted Human Reproduction Bill 2017 is thus a welcomed development. However further reading of the Bill reveals that it is restrictive in nature and likely to stifle research in Ireland. This paper will discuss the legal, ethical and scientific developments that have occurred since the CAHR report and the impact, if any, they have had on the development of this Bill. It will critically reflect on provisions of the Bill as they relate to ESCR and make a number of suggestions for reform.

Introduction

Since the announcement of the creation of the first embryonic stem cell line almost 20 years ago,¹ attention has focused on the ethical and legal status of the research. Found in an early-phase embryo, an embryonic stem cell has the potential to develop into any cell type in the body and can potentially be engineered to produce new tissues or organs, bringing new hope to those suffering from degenerative illness as well as other incurable diseases. However embryonic stem cell research (ESCR) has faced much resistance to embryonic stem cell research as the debate on the moral status of the embryo continues. Disagreement persists as to whether the embryo is considered to be life, a clump of cells or having some other intermediate status.² Throughout the world, jurisdictions have considered the legal, ethical and social implications of the research that has resulted in regulations on this matter.³ Yet Ireland remains one of the few countries in Europe without any legislative scheme or national oversight of this research. This has resulted in a peculiar situation whereby the embryo *in vivo* has full constitutional protection through Article 40.3.3, but since the Supreme Court in *Roche v*

¹ J Thomson, J Itskovitz-Eldor, S Shapiro, M Waknitz, J Swiergiel, V Marshall, J Jones, 'Embryonic Stem Cell Lines Derived from Human Blastocysts' (1998) 282 *Science* 1145-7.

² See Congregation for the Doctrine of the Faith, *Instruction Dignitas Personae on Certain Biological Questions* (2008). ² D Evans (ed), *Conceiving the Embryo: Ethics, Law and Practice in Human Embryology* (Martinus Nijhoff Publishers 1996). P Singer, K Dawson, 'IVF technology and the argument from potential' (1988) 17 *Philosophy and Public Affairs* 87. C Cohen, *Renewing the Stuff of Life: Stem Cells, Ethics, and Public Policy* (OUP 2007). M Lockwood, 'When Does Life Begin?' in M Lockwood (ed), *Moral Dilemmas in Modern Medicine* (OUP 1985). N Poplawski, G Gillett, 'Ethics and Embryos' (1991) 17 *Journal of Medical Ethics* 62

³ R Isasi, B Knoppers 'Mind the Gap: Policy approaches to Embryonic Stem Cell and Cloning in 50 Countries' (2006) 13 *European Journal of Health Law* 9-25.

*Roche*⁴ clarified that the embryo *in vitro* is not protected under this Article, it has had no protection in law.

The Commission on Assisted Reproductive Human Reproduction (CAHR) published a comprehensive government commissioned report in 2005, but successive governments failed to bring forth any legislation until October 2017 when a General Scheme of Assisted Human Reproduction Bill 2017 was introduced. In the intervening 12 years since the publication of the CAHR and the General Scheme of this Bill, there has been considerable scientific developments in the realm of ESCR and embryo research, constitutional developments on the status of the embryo in Irish law, and developments on the funding and patenting of ESCR at a European level.

On the face of it, this Bill is a welcomed development as an attempt to clarify the status of ESCR in Ireland. It should remedy the anomalous situation that sees Ireland funding ESCR at a European level, but preventing scientists from accessing European funds. It also should serve as a much needed opportunity to have a national debate on these issues in light of the intervening twelve years since the CAHR report. However, while the Bill does permit ESCR, a closer reading of it reveals that it is restrictive in nature and likely to stifle research. It also fails to adequately consider the legal, ethical and scientific developments that has taken place since the publication of this Bill. To remedy this, this paper will consider the legal and ethical developments that have since taken place. It will discuss induced pluripotent cell (iPSC) research and whether this erodes the need for ESCR. It will consider the legal status of the embryo arising from the *Roche v Roche* case and whether a European consensus has begun to emerge on the status of the embryo. Finally it will reflect on the impact that these developments have had on the General Scheme of the Bill.

Ethical considerations & iPSCs

Found in an early-phase embryo, an embryonic stem cell has the potential to develop into any cell type in the body and can potentially be engineered to produce new tissues or organs, bringing hope to those suffering from degenerative illness as well as other incurable diseases.⁵ As well as potential therapeutic benefit, stem cells may help us better understand the developmental process of the embryo and the causes of certain defects. The chief concern with ESCR is that it involves the destruction of the embryo. Herein lies what Devolder calls ‘The Problem’:

‘Either one supports embryonic stem cell research and accepts resulting embryo destruction, or one opposes embryonic stem cell research and accepts that the potential benefits of the research will be forgotten.’⁶

Presented as such, we seem to have a choice between destroying an embryo for its potential medical benefits and protecting the embryo at all costs. For many the answer is less clear due to the uncertain status of the embryo; they may want the benefit of ESCR but may feel unease with embryo destruction.

⁴ *Roche v Roche* [2010] 2IR 321.

⁵ For more on the potential of the research see Editorial, ‘The Promise of Stem Cells’ (2004) 7 *Nature Neuroscience* 1013.

⁶ K Devolder *The Ethics of Embryonic Stem Cell Research* (Oxford University Press, 2015), 2.

Although the moral status of the embryo has been discussed in detail elsewhere,⁷ some of the main discussion points are worth noting here.

The embryo may have the same moral status as that of a human being and irrespective of its instrumental value it can never be destroyed.⁸ The practical implications of this are that all embryos fertilised *in vitro* must be implanted and certain contraceptive practices such as the morning after pill that are currently widely utilised in Ireland must be prohibited.

Others see the development of the early embryo into the foetus and gradually into the birth of a child, as part of a process upon which an embryo gradually acquires status as it develops. Known as the gradualist approach, this was the position adopted by the Irish Council on Bioethics, which felt that the embryo had significant but not full moral status and justified their position on the 'potentiality argument';⁹ it is because of their potential to develop into a human being that embryos have some moral status and there must therefore be limits on the use of embryos for research purposes.

Lockwood argues that debates on the moral status of the embryo rarely achieve much as they are usually inconclusive.¹⁰ This is perhaps valid and may explain why differences in regulatory approaches have emerged. Approaches to the regulation of ESCR have ranged from relatively liberal policies in the UK, quite restrictive policies such as in Germany that only permit ESCR on imported embryonic stem cell lines, to what could be perceived to be intermediate policies as demonstrated in France that permit ESCR on embryonic stem cell lines created from left over embryos. Rarely are policies entrenched in a particular viewpoint of the embryo, but rather they reflect a political compromise.¹¹ Since the publication of the CAHR report, scientists have developed and begun to understand the potential of iPSCs. iPSCs are reprogrammed adult stem cells that are pluripotent and have many similar characteristics to human embryonic stem cells (hESCs).¹² These cells do not involve the destruction of an embryo and as such, do not attract the same ethical controversy.¹³ Thus if we support the aims of ESCR, but have unease with the destruction of the embryo in the process, iPSCs could possibly provide an ethically acceptable alternative.

A considerable amount of effort has gone into exploring this possible avenue of research,¹⁴ however, if we still want to achieve the goals of ESCR, focusing on iPSCs alone will not achieve this. There are a

⁷ Irish Council on Bioethics *Ethical, Scientific and Legal Issues Concerning Stem Cell Research* (2008). Commission on Assisted Human Reproduction *Report of the Commission on Assisted Human Reproduction* (2005). F Gough, 'Human Embryonic Stem Cell Research in Ireland: Ethical and Legal Issues' (2011) 11 (4) *Medical Law International* 262-283.

⁸ Congregation for the Doctrine of the Faith, *Instruction Dignitas Personae on Certain Biological Questions* (2008).

⁹ Irish Council on Bioethics *Ethical, Scientific and Legal Issues Concerning Stem Cell Research* (2008), 41.

¹⁰ M Lockwood n4, 9-10.

¹¹ D Smith, 'Stuck in the Middle' (2006) 36 *The Hastings Centre Report* 32. R Charo, 'Bush's Stem Cell Compromise: A Few Mirrors?' (2001) 34 *The Hastings Center Report* 6

¹² K Takahashi, S Yamanaka, 'Induction of Pluripotent Stem Cells from Mouse Embryonic and Adult Fibroblast Cultures by Defined Factors' (2006) 131 *Cell* 861. K Takahashi *et al* 'Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors' (2007) 131 *Cell* 861. J Yee, 'Turning Somatic Cells into Pluripotent Stem Cells' (2010) 3(9) *Nature Education* 25, 25.

¹³ M Roa, M Condic, 'Alternative Sources of Pluripotent Stem Cells' (2008) 17 *Cells' Stem Cells and Development* 4.

¹⁴ J Hanley, G Rastegarlar, A Nathwani, An introduction to induced pluripotent stem cells (2010) *British Journal of Haematology*, 151, 16-24, 17.

number of differences between hESCs and iPSCs and the impact that these differences may have on the function of the cells and safety is currently unclear.¹⁵ These distinctions include genetic and epigenetic differences and the fact that the behaviour of each type of cell is more complex than previously thought.¹⁶ Further, research on both types of cells is necessary to both understand and harness the potential of iPSCs and it is now considered that, rather than replace hESCs, iPSCs should complement them.¹⁷ ESCR also began almost a decade earlier than research on iPSCs and is thus more advanced. For now, hESCs remain the ‘gold standard’ to which iPSCs will be compared¹⁸ and realising the potential of iPSCs requires ongoing ESCR. Rather than reducing the need for hESCs, Devolder suggests that iPSCs indirectly encourages ESCR, as hESCs will continue to be used as the control group.¹⁹ However iPSC research in and of itself does not face the same ethical considerations as ESCR and it is for that reason the International Society for Stem Cell Research has stated that it does not require specialised review and it is also currently permitted in Ireland.²⁰

Legal status of the embryo in Ireland

Since 1983 the ‘unborn’ have been constitutionally protected with the insertion of the 8th amendment:

‘The State acknowledges the right to life of the unborn and, with due regard to the right to life of the mother, guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate that right.’

The purpose of Article 40.3.3 was to constitutionally prohibit abortion, but with the ‘unborn’ remaining undefined in Irish law, there had been much uncertainty as to whether the amendment went beyond abortion and protected the embryo *in vitro*. This lack of discussion as to the definition of the unborn and its impact, if any, on the embryo is one of the many shortcomings of the formulation and debate around the 8th amendment. The birth of the first child through IVF had occurred five years previously, and arguably Parliament ought to have considered the wording of the amendment in light of this development. A proposed amendment in the Seanad to explicitly state that constitutional protection applies after implantation would have clarified the constitutional protection (*vis a vis* the embryo *in vitro*) but this was rejected.²¹

Within a decade, the amendment became the subject of cases litigated in the High Court, Supreme Court and ultimately to the European Court of Human Rights,²² but its possible impact on embryos *in vitro* was largely ignored until the formation of the Constitution Review Group in Ireland in 1995. The Group called for a definition to clarify, amongst other things, the impact of the amendment on assisted

¹⁵ EuroStemCell Report *Stem Cell Research: Trends and Perspectives on the Evolving International Landscape* (2013), 16 quoting an interview with Yamanaka.

¹⁶ D Robinton, G Daley ‘The Promise of Induced Pluripotent Stem Cells in Research and Therapy’ (2012) 481 *Nature* 295–305, 300.

¹⁷ *Ibid.*

¹⁸ J Aninka Mansnerus Bioethical and legal perspectives on cell reprogramming technologies *Medical Law International* 2016, Vol. 16(3-4) 206–228, 214. C Ho *Juridification in Bioethics: Governance of Human Pluripotent Cell Research* (World Scientific, 2016), 69.

¹⁹ K Devolder n 7, 129.

²⁰ International Association for Stem Cell Research, *Guidelines for Stem Cell Research and Clinical Translation* (2016), para 2.1.

²¹ Seanad Debates 1983, vol 100, col 1092.

²² For example see *AG v X* [1992] 1 IR 1 53-54. *A, B and C v Ireland* [2010] EHRR 2032.

reproductive technologies and by implication, ESCR.²³ Aware of the growing need to regulate assisted reproductive technologies, the government appointed the Commission on Assisted Human Reproduction in 2000.²⁴ Its 2005 report and a subsequent report by the Irish Council for Bioethics in 2008 considered the legal status of the embryo.²⁵ Both reports expressed the view that although the matter would need clarification from the Supreme Court, the embryo *in vitro* is not protected under Article 40.3.3.

Clarification came in *Roche v Roche* when the High Court and Supreme Court were asked to consider whether the protection under Article 40.3.3 extended to embryos *in vitro*.²⁶ The case concerned a couple who underwent IVF treatment but subsequently separated. There were a number of frozen embryos left over which Mrs Roche wanted to implant, contrary to the wishes of Mr Roche. The Court had to determine, amongst other issues, whether the embryo *in vitro* came under the definition of the 'unborn' and if so, whether it was constitutionally protected. Both courts held that it is only upon implantation that an embryo is constitutionally protected. The courts were very clear that this case was not concerned with the moral status of the embryo or determining when life begins²⁷ as there is 'no definite scientific or medical answer to that question'.²⁸ In essence, the courts felt that the constitutional and moral questions were distinct and their focus was on the interpretation of the 8th amendment.

In considering the definition of the unborn, the courts noted that although the 8th amendment was inserted to constitutionally prohibit abortion, the text itself does not mention abortion but rather confers on the unborn a positive right to life and arguably this text goes further than simply constitutionally prohibiting abortion. Binchy is unequivocal that the purpose of the amendment was wider and focused on protecting life in the early stages that includes the embryo *in vitro*.²⁹ Murray CJ, in determining that the issue was not justiciable, considered that if the intention was to limit the confines of the amendment to abortion, the Constitution would have contained an express prohibition, much like it did when the Constitution contained an express prohibition on divorce. Rather, the focus of the amendment was to afford a positive protection on all forms of early human life.³⁰

In examining the historical purpose of the amendment and subsequent judgments, the majority of the Supreme Court noted that the courts had consistently endorsed the purpose of the 8th amendment as being to constitutionally prohibit abortion.³¹ This was, however, the first case that required a consideration of the meaning of 'unborn' beyond the confines of a termination of pregnancy. Much weight was given to the phrase 'right to life of the mother' and the link between the unborn and the mother. This created a constitutional relationship between the mother and the unborn and it was only

²³ Constitution Review Group, *Report of the Constitution Review Group* (1996) 275. The first embryonic stem cell line was not derived until 1998 and thus did not form part of the analysis of the Review Group.

²⁴ Commission on Assisted Human Reproduction *Report of the Commission on Assisted Human Reproduction* (2005).

²⁵ Irish Council for Bioethics *Ethical, Legal and Scientific Issues Concerning Stem Cell Research* (2008)

²⁶ *Roche v Roche* [2010] 2IR 321.

²⁷ *Ibid* 338, *per* McGovern J, 351 *per* Murray CJ,

²⁸ *Ibid* 383 *per* Geoghegan J.

²⁹ W. Binchy, 'Article 40.3.3 of the Constitution: Respecting the Dignity and Worth of Human Beings', in J. Schweppe, *The Unborn Child, Article 40.3.3 and Abortion in Ireland* (Dublin: The Liffey Press, 2008), p. 195.

³⁰ *Roche v Roche* [2010] 2IR, 347-348.

³¹ *Ibid*

when this relationship existed that Article 40.3.3 was applicable.³² Thus any rights of the unborn under Article 40.3.3 were inextricably linked to those of the mother. This relationship was physical and only applied to a woman in the context of pregnancy and thus to an embryo upon implantation.

Yet such an interpretation of the Constitution is at odds with a purposive interpretation of Article 40.3.3. Such an interpretation does not view the eighth amendment as constitutionally prohibiting abortion, but prohibits abortion through affording the unborn the right to life and with that, the best interests of the unborn is a consideration.³³ Until such time as Article 40.3.3 is repealed, this protection of the unborn may extend to keeping a clinically dead pregnant woman alive if it is in the best interests of the foetus.³⁴ It is thus clear that the remit of Article 40.3.3 goes beyond abortion and interferes with other elements of reproductive care. This does not necessarily imply that it is intended to extend to embryos *in vitro*.

However it is not just Article 40.3.3 that must be considered in the context of the embryo *in vitro*. The right of marital privacy as discussed in *McGee v Attorney General*,³⁵ is constitutionally protected and Denham J thus considered Article 40.3.3 within the context of Article 41.1.2. A finding that embryos come under the definition of unborn would require state interference to ensure that all embryos are implanted.³⁶ Not only would this outlaw certain contraceptive practices, but it would also require the implantation of all embryos created through IVF, irrespective of viability and irrespective of the wishes of the parents. In view of Article 41.1.2, Denham J considered that this was outside the competence of the State, as a decision on whether or not to have children, including through IVF, is a private matter for parents.³⁷ Consideration should also be given to the judgment of Finlay CJ in *AG v X* who stated that that qualification in Art 41.1.2? 'as far as practicable' means that the Court has the discretion not to 'make orders which are futile, impractical or ineffective'.³⁸ Any decision that would have rendered common contraceptive practices illegal would certainly be futile, impractical or ineffective.

The courts were unequivocal that beyond the constitutional matter at hand, the issue as to the status of the embryo is a matter for the government to resolve. The difficulty of the task was acknowledged as arguments that an embryo is life will be countered with the importance of embryo research for medical purposes.³⁹ However, while such matters require development of policy in a matter that is fraught with legal, ethical and moral complexity, Hardiman J noted that 'the fact that difficulties are raised does not absolve the legislature from the obligation'.⁴⁰ The learned judge stressed the need for legislation as 'Ireland may become by default an unregulated environment for practices that may prove controversial or, at least, give rise to a need for regulation'.⁴¹

³² *Ibid* 370, *per* Denham J.

³³ See PP V HSE [2014] IEHC 622

³⁴ *Ibid*. See also Fiona de Londras, Constitutionalizing Fetal Rights: A Salutory Tale from Ireland, 22 Mich. J. Gender & L. 243 (2015).

³⁵ *McGee v. Attorney General* [1974] I.R. 284.

³⁶ *Roche v Roche* [2010] 2IR 321, 372.

³⁷ *Ibid*.

³⁸ *AG v X* [1992] 1 IR 1.

³⁹ *Ibid* 393, *per* Geoghegan J.

⁴⁰ *Ibid* 383.

⁴¹ *Ibid*.

It is thus clear that legislation on this matter is necessary to clarify the status of the embryo and ESCR. Despite its clear intention to leave decisions as to the status of the embryo with the legislature, there are a number of points worth noting.

Fennelly J reflected in *Roche* that if they continue to abdicate their responsibility, the courts may be forced to consider the issue again. Although there is no constitutional provision explicitly referring to embryos, Fennelly and Geoghegan JJ hinted that an embryo could enjoy constitutional protection under some other article of the Constitution. This may perhaps come from one of the unenumerated rights under Article 40.3,⁴² but is as yet unexplored. However considering the importance of Article 41.1.2 in this debate, it is unlikely that the embryo would have full constitutional protection and the legislature should be mindful that any attempts to give full protection to an embryo would be unlikely to withstand constitutional challenge.

A determination of the status of the embryo is likely to be grounded on the notion of respect for the embryo with Hardiman, Geoghegan and Fennelly JJ stating that the embryo is entitled to respect. Hardiman J considered that this respect lies in its ability to become life⁴³ and in the view of Geoghegan J that the State's failure to indicate how this respect should be given 'is undesirable and arguably contrary to the spirit of the Constitution'.⁴⁴ Fennelly J supported this view that there is a constitutional obligation to provide respect for the embryo in law.⁴⁵ McGuinness and Ui Chonnachtaigh argue that it would be unusual for a Constitution to give such strong protection to an embryo *in utero* and simultaneously give none to the embryo *in vitro*.⁴⁶ However, it is likely that while the protection may differ, the respect the courts seems to afford to embryos *in vitro* and comments that the state is arguably failing in its constitutional duty to protect the embryo, would suggest that there is some, albeit unexploited, constitutional protection for the embryo *in vitro*.

Embryo research in Europe

While the protection of embryos in Ireland remains unsettled, there have been a number of developments in the European Union. The competences of the EU traditionally lie in creating an internal market and economic union,⁴⁷ but the Commission has begun to take a more active role in health and technology since 2002 with the adoption of programmes on public health.⁴⁸ The EU has also committed itself to becoming a bigger player in the world economy through increased investment in research⁴⁹ and biotechnology⁵⁰ with the aim of improving public health. As part of this commitment

⁴² I Clissmann, J Barrett 'The Embryo in vitro after Roche v Roche: What Protection is Now Offered?' (2012) 18(1) *Medico-Legal Journal of Ireland* 13-19, 17.

⁴³ *Roche v Roche* [2010] 2IR 321, 382.

⁴⁴ *Ibid* 393.

⁴⁵ *Ibid* 395.

⁴⁶ S McGuinness, S Ui Chonnachtaigh 'Implications of Recent Developments in Ireland for the Status of the Embryo' (2011) 20 *Cambridge Quarterly of Healthcare Ethics* 396-408, 405.

⁴⁷ Article 3 (ex Art 2).

⁴⁸ Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008), Decision No 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-13)

⁴⁹ Communication on working together for growth and jobs - a new start for the Lisbon strategy COM (2005) 24 final.

⁵⁰ Communication on promoting the competitive environment for industrial activities based on biotechnology within the community SEC (91) 629 final.

to research and health, there has been activity on biological materials,⁵¹ clinical trials⁵² and the patenting of biotechnology.⁵³ However it is economic integration, not moral integration, which is the purpose of the EU⁵⁴ and there has been no attempt to harmonise health research ethics, with individual Member States left to develop their own policies on ESCR.

The emergence of biotechnology has blurred the distinction between regulating technology and regulating ethics. Introducing policies on biotechnology, in particular controversial technologies, can implicitly endorse a particular ethical viewpoint, creating a tension between the need to harmonise biotechnology to further economic integration, and the need to respect the constitutional traditions of Member States. Ethics and biotechnology are not mutually exclusive, and the ethical challenges posed by new technologies are at the forefront of any regulatory discussion. Introducing an EU-wide policy that permits ESCR, even if subject to the laws of the Member State, could imply an EU acceptance of the research and could suggest the emergence of a European consensus on this matter.

Issues pertaining to the status of the embryo and embryo research are notoriously difficult to settle at a national level and become even more complicated at a supranational level where there are differing constitutional traditions and cultural values to consider. Nevertheless, policy that impacts on the embryo has been developed.

Funding ESCR in Europe

EU funding of scientific research is primarily channeled through programmes known as ‘Framework Programmes’ (FPs). FPs are the main financial tools through which the EU supports research and development activities, covering almost all scientific disciplines. FP6 (2003-2006), adopted in 2002, was the first FP in which it was agreed to fund ESCR, a policy continued under FP7 and Horizon2020. Despite the decision to fund the research in principle in 2002, a moratorium was agreed between the European Commission and the Council so as to give them time to put in place detailed provisions to implement this new policy.⁵⁵ During these discussions, the Commission was at pains to point out that the development of a funding policy for ESCR was ‘not about establishing EU legislation on ethical questions’, but rather its focus was on fostering collaborations to promote research that benefits the

⁵¹ Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. Regulation on advanced therapy medicinal products and amending Directive 2001/83/EC.

⁵² Directive 2004/27/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.

⁵³ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

⁵⁴ M Facale, A Plomer ‘Fundamental disjunction in the EU legal order on human tissue, cells and advanced regenerative therapies’ (2009) 16 *Maastricht J Eur & Comp L* 89-112, 94.

⁵⁵ Commission of the European Communities (2003) Proposal for a Council decision amending decision 2002/834/EC on the specific programme for research, technological development and demonstration: ‘Integrating and strengthening the European research area’ (2002–2006). Brussels, 9.7.2003, COM (2003) 390 final 3.

citizens of the EU 'while respecting national rules and values'.⁵⁶ The Commission thus committed itself to funding ESCR, leaving Member States free to consider the ethical issues.⁵⁷

However, due to the nature of the research, it was not possible to ignore the ethical considerations and, perhaps mindful of the debate within Member States, a number of rules were adopted. Collaborations were encouraged to avoid the duplication of research and the unnecessary destruction of embryos. Only spare embryos left over after IVF treatment prior to 27 June 2002 could be used to create an embryonic stem cell line⁵⁸ and it had to be proven that other research methods, such as adult stem cell research, would not yield the desired results of the research.⁵⁹ Importantly, research that is prohibited in a Member State will not be funded.⁶⁰ Thus, irrespective of this agreed funding framework, funding will only be granted if ESCR is permitted in the Member State and the Commission's policy seems to align itself somewhat with Article 18 of the Oviedo Convention. Member States are free to decide on the fundamental issue of whether to permit ESCR, but the creation of embryos for research purposes is not permitted.

Instrumental in the drafting of the guidance for FP6 and FP7 was the European Group on Ethics (EGE), the body tasked with providing the Commission with ethical guidance for new technologies. Opinion 15 considered the creation of embryos for research purposes to be ethically unacceptable when there are spare embryos available⁶¹ and in 2007, on request from President Barroso, the EGE issued *Recommendations on the ethical review of hESC FP7 research projects*.⁶² Similar to the stance of the Commission, the EGE stressed that they were not looking at the ethics of ESCR, but rather the focus was on the implementation of a funding policy.⁶³ Thus, both the approach of the EGE and the Commission to ESCR has been similar: both turned their attention away from the ethical debate towards the implementation of a funding policy.

Importantly, although not binding on Member States, this funding framework represents the first European statement from the Commission on what can be done with the human embryo. It could also represent some, albeit limited, consensus on ESCR within Europe. The guidelines only apply to projects in receipt of European funds, but they are nonetheless an ESCR policy, a policy agreed by all Member States which permits ESCR in certain circumstances. Interestingly it is also a policy that was supported by the Irish government, which stated that should ESCR be permitted, it must be conducted with

⁵⁶ Commission, Commission report on embryonic stem cell research provides basis for discussion on ethics IP/03/506, Brussels, 7 April 2003.

⁵⁷ 'Inter-institutional debate on stem cell research reveals extent of ethical split within Europe' 25 April 2003 <http://cordis.europa.eu/search/index.cfm?fuseaction=news.document&N_LANG=EN&N_RCN=20147&pid=34&q=D947BD405B4FECE44933948AB2209F56&type=sim> [accessed 16 June 2012].

⁵⁸ Commission, *Commission report on embryonic stem cell research provides basis for discussion on ethics* IP/03/506, Brussels, 7 April 2003, 8.

⁵⁹ Ibid.

⁶⁰ Ibid para 1.1.

⁶¹ Opinion of the European Group on Ethics in Science and New Technologies to the European Commission Opinion #15 (2000) Ethical Aspects of Human Stem Cell Research and Use, para 2.7.

⁶² The European Group on Ethics in Science and New Technologies to the European Commission Recommendations on the ethical review of hESC FP7 research projects Opinion #27 (2007).

⁶³ Ibid 3.

proper regulation and safeguards in place.⁶⁴ At the time, the government was awaiting the report of the CAHR and the status of the embryo had not been clarified by the Supreme Court, yet the Irish government approved these rules through a formal endorsement of the policy, and indirectly through the contribution of Irish taxes towards embryo research in Europe. EU funds cannot be spent on the derivation of the stem cell line and will therefore not fund the destruction of the embryo, but this policy is an acceptance of the research by both the Irish government and the EU. It also provides us with the first indication as to what the Irish government considers to be acceptable policy in the realm of ESCR.

Achieving this consensus is significant considering the diverging views across Member States on this issue, and arguably this minimum level of consensus is all that can be achieved considering the differing legal, ethical and cultural differences across the EU.⁶⁵ No further harmonisation on ESCR should be attempted as it is unlikely to be possible to achieve, nor desirable to attempt. A framework such as this, which provides a funding mechanism for the research but leaves Member States with the authority to permit or prohibit the research, is perhaps best in light of the differing approaches to ESCR across Member States, yet for Irish policy, it brings many questions and contradictions. Ireland is not only permitting, but funding ESCR in other Member States, yet has continued to prohibit any such activities on Irish soil. It is a policy that lacks ethical consistency and is without legal foundation.

Patenting of ESCR in Europe

Irish policy makers have been undeterred by any legal or ethical justifications to introduce embryonic stem cell policy. However, favourable patenting policies for ESCR could bring an economic return and provide an economic incentive to provide regulatory oversight for this research in Ireland.

Biotechnological research is expensive and cannot be dependent upon public funding only. Favourable patenting policies that make it possible to obtain a return on investment can encourage private investment in the research as a patent gives the inventor exclusive rights to monopolise their invention for 20 years.⁶⁶ It can stimulate medical research as it allows for compensation of research, and patients can benefit from the developments in diagnostics and therapeutics.⁶⁷ The patent holder can sell their patent under a licence agreement, opt to exploit the invention, or simply do nothing with the patent, while still preventing others from using the patented product. The Nuffield Council notes that the securing of funding through the promise of a patent is likely to play a significant role 'in shaping the dynamics of scientific research and technological innovation'.⁶⁸ Thus if inventions arising out of ESCR can be patented, scientists based in Ireland may be able to attract private funding.

⁶⁴ Seanad Debates 19 November 2003 Vol 174 No.14 col 1096. Smyth J (2006) EU to provide stem-cell research funding. *The Irish Times*, 25 July 2006 <http://www.irishtimes.com/news/eu-to-provide-stem-cell-research-funding-1.1262868> [accessed 4 January 2017].

⁶⁵ S Halliday, 'A comparative approach to the regulation of human embryonic stem cell research in Europe', (2004) 12(1) *Medical Law Review* 40-69, 57.

⁶⁶ R Noll *The Politics and Economics of Implementing State-Sponsored Embryonic Stem Cell Research* in A Levine (ed) 'States and Stem Cells: the Policy and Economic Implications of State-Funded Stem Cell Research' (Princeton, 2006), 28. For an overview and critique of the patent system, see M Llewelyn 'Schrodinger's Cat: An Observation on Modern Patent Law' in P Drahos (ed) *Death of Patents* (Lawtext Publishing, London, 2005).

⁶⁷ Group of Advisors on the Ethical Implications of Biotechnology *Ethical Aspects of Patenting Involving Elements of Human Origin*.

⁶⁸ Nuffield Council on Bioethics *Genome Editing: An Ethical Review* (2016), para 2.13.

Due to the increasingly important role that biotechnology is playing in industries, the Biotechnology Directive was introduced to protect biotechnology inventions to ensure the continuing development of Community industries.⁶⁹ The Commission sought to remove any barriers to the patenting of biotech inventions through this directive and its purpose was to harmonise this area of law to promote research and develop biotechnology.⁷⁰ However, despite the perceived importance of biotechnology and the need for an EU directive that specifies that biotechnological inventions are patentable, due to pressure from the Green lobby, the European Parliament exercised its veto power⁷¹ and rejected the first draft of the Directive in 1995 for failing to contain a reference to morality.⁷² A new version proposed by the Commission later that year included general and specific exclusions on public morality and was eventually passed in 1998.⁷³

Importantly for ESCR, Article 6(2)(c) prohibits the patenting of ‘uses of human embryos for industrial or commercial purposes’, but once again embryos are not defined and it is also not clear whether embryonic stem cell lines came under the definition. The uncertainty over the patenting of ESCR is in part due to ESCR being in its infancy when the Directive was drafted,⁷⁴ but securing agreement would likely have been fateful to the Directive. Further guidance was necessary but the EGE was of the opinion that a decision on the patenting of ESCR inventions was closely linked to defining an embryo and both should be determined by national legislation in accordance with its own laws and values.⁷⁵ Thus further guidance or harmonisation on this issue was deemed to be unnecessary.⁷⁶ Once again there was broad consensus, but disagreement with the detail.

This perspective was challenged in the case of *Brustle v Greenpeace*⁷⁷ where the Court of Justice of the European Union (CJEU) was asked by the Federal Court of Justice of Germany to clarify the scope of Article 6(2)(c). The Court was asked to consider three specific questions: the definition of the embryo under the Directive; whether commercial exploitation for scientific research comes under the definition of ‘uses of human embryos for industrial or commercial purposes’; and whether an invention that uses an embryo at any stage be precluded from patentability.⁷⁸

Concerning the first question, the Court noted that the lack of a definition coupled with a lack of reference to national laws implies that the term must have a uniform definition across the EU.⁷⁹ For the Court, this conclusion was supported by the aims and objectives of the Directive⁸⁰ which sought

⁶⁹ European Parliament Resolution on Patents for Biotechnology Inventions (October 2005) OJ 272 E/440.

⁷⁰ Case C-377/98 *Netherlands v European Parliament* [2002] ECR 574 para 27.

⁷¹ Article 251 EC. See also RS Crespi ‘The Human Embryo and Patent Law: A Major Challenge Ahead’ [2006] 28 *European Intellectual Property Review* 569-575. D Curley, A Sharples ‘Patenting Biotechnology in Europe: The Ethical Debate Moves On’ [2002] *European Intellectual Property Review* 565, 565.

⁷² D Curley, A Sharples n 71.

⁷³ RS Crespi, n 71, 571.

⁷⁴ M Rowaldson ‘WARF/Stem cells (G2/06): the ordre public and morality exception and its impact on the patentability of human embryonic stem cells’ (2010) 32 *European Intellectual Property Review* 67-76, 67.

⁷⁵ Opinion on the European Group of Ethics on Science and New Technologies to the European Commission *Ethical Aspects of Patenting Inventions Involving Human Stem Cells* 7 May 2002

⁷⁶ *Ibid.* See also Final Report from the Commission to the European Parliament and the Council Developments and implications of patent law in the field of biotechnology and genetic engineering COM(2005) 312, para 2.2; University of Nottingham *Stem Cell Patents: European Patent Law and Ethics* (2006).

⁷⁷ [2011] ECR I-9821.

⁷⁸ *Ibid* para 23.

⁷⁹ *Ibid* para 26.

⁸⁰ *Ibid* para 27.

to harmonise patent protection across the EU.⁸¹ While recognising that there were debates across Member States as to the status of the embryo, the Court was of the opinion that it was required to give a legal decision on the definition of the term ‘human embryo’ in the context of the Directive.⁸² In other words, the Court had to provide a uniform definition for the embryo that would bind all Member States when considering patent applications under the Biotechnology Directive. Significantly, the Court ruled that while the purpose of the Directive was to promote investment, the use of biological material must have regard for fundamental rights and in particular dignity, thus the term embryo must be given a broad definition.⁸³ Therefore, under the Directive, the CJEU ruled that a human embryo is formed once an egg is fertilised,⁸⁴ but declined to state whether an embryonic stem cell line is considered an embryo under the Directive. This is a decision for the national courts to make in light of scientific developments.⁸⁵

Regarding the second question, the Court ruled that the use of embryos for scientific purposes is defined as ‘the use of human embryos for industrial or commercial purposes’⁸⁶ and that only uses ‘for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it being patentable’ can be patented.⁸⁷ Finally and most importantly for ESCR, the Court stated that if an embryo is destroyed in the making of the invention, it is unpatentable, irrespective of how far removed the destruction of the embryo was from the patent application.⁸⁸ The Court considered that the commercialisation of an invention that destroyed an embryo in its making would be an affront to dignity.

The European Patent Office (EPO) had previously decided in the *Wisconsin Alumni Research Foundation (WARF)* case that if an embryo was destroyed in the making of an invention, it was unpatentable.⁸⁹ However this decision is surprising, as it had previously been established policy that due to the presumption of patentability, exceptions to this general principle of patentability ought to be interpreted narrowly.⁹⁰

Prior to the *Brustle* decision some limited consensus perhaps had emerged in Europe: that is, that the embryo was deserving of protection and that the definition of an embryo was for individual countries to decide. There was a push to limit research to spare embryos left over after IVF, but this was not

⁸¹ Recital 4 of the Biotechnology Directive.

⁸² *Brustle v Greenpeace* [2011] ECR I-9821 para 30.

⁸³ *Ibid* para 34.

⁸⁴ *Ibid* para 35.

⁸⁵ *Ibid* para 38.

⁸⁶ *Ibid* para 42.

⁸⁷ *Ibid* para 46.

⁸⁸ *Ibid* para 52.

⁸⁹ *Wisconsin Alumni Research Foundation (WARF) G 0002/06*. For commentary on this case see S Sterckx, ‘The European Patent Convention and the (Non)Patentability of Human Embryonic Stem Cells) the WARF Case’ [2008] 4 *Intellectual Property Quarterly* 478-495, M Rowaldson n 78, J Shun, ‘Moral Disharmony: Human Embryonic Stem Cell Patent Laws, WARF and Public Policy’ (2010) 33 *Boston College International and Comparative Law-Review* 153 and S Sterckx, J Cockbain, ‘Assessing the Morality of the Commercial Exploitation of Inventions Concerning Uses of Human Embryos and the Relevance of Moral Complicity: Comments on the EPO’s WARF Decision’ (2010) 7 *SCRIPTed* 83-103.

⁹⁰ A Warren-Jones ‘Patenting DNA: A lot of Controversy over a little Intangibility’ [2004] 12 *Medical Law Review* 97-124, 102. G Porter ‘The Drafting History of the European Biotechnology Directive’ in A Plomer, P Torremans (eds) *Embryonic Stem Cell Patents: European Patent Law and Ethics* (Oxford, Oxford University Press, 2010), 7.

successful. Thus the judgment in *Brustle* is somewhat surprising. Despite the clear lack of consensus across Europe and the lack of a definition in the Directive, the Court held that an embryo is formed at fertilisation. Although its decision is confined to commercialisation, the decision is a worrying restrictive step, particularly in light of the differing legislative schemes of Member States.⁹¹

Second, the Court based its reasoning on the protection of dignity. In other words, to ensure respect for human dignity, a fertilised egg must be considered an embryo. Due to the wide level of protection needed, an embryo that is destroyed at any stage in the making of an invention cannot be patented; according to the CJEU, to commercialise ESCR would be contrary to human dignity. Consensus on these issues, particularly on the protection of embryos, has been notoriously difficult to achieve, and it is questionable whether more than the literal meaning should have been inferred from the Directive. The expansive nature of this decision is all the more surprising considering that the Directive was unlikely to have been drafted with ESCR in mind and it is unclear whether the drafters considered it. It is a rather wide interpretation of a provision that was to be narrowly interpreted, requiring no moral decision to be made.⁹² If a moral decision is to be made on the destruction of the embryo, it is by the Member States under Article 6(1). A decision that hESCs do not fall under the exclusions would have not precluded Member States from prohibiting the invention under Article 6(1) in line with its own legal and ethical framework, that is reflective of its own cultural values.

This decision has been somewhat limited by *International Stem Cell Corporation v Comptroller General of Patents*.⁹³ The CJEU held that to constitute a human embryo, the entity must have the capacity to develop into an embryo and this is a matter for the national courts to decide.⁹⁴ However, the crux of the *Brustle* decision, that the destruction of an embryo at any point in the making of the invention renders it unpatentable, remains in place.

Council of Europe

There have also been some developments within the Council of Europe on this matter. Article 2 of the European Convention on Human Rights (ECHR) protects the right to life. Although the scope of that right is undefined, the European Convention on Human Rights has consistently left it within the margin of appreciation for Member States to determine whether that should apply to the foetus as there is no consensus on a scientific or legal definition of the beginning of life.⁹⁵ *Evans v United Kingdom* concerned the disposition of frozen embryos and the Court ruled unanimously that the issue as to the right to life comes within the margin of appreciation of Member States.⁹⁶ The Court also noted:

‘Where, however, there is no consensus within the Member States of the Council of Europe, either as to the relative importance of the of the interest at stake or as to the best means of protecting it, particularly where the case raises sensitive moral or ethical issues, the margin will be wider.’⁹⁷

⁹¹ For comparison of approaches, see S Halliday, n 65.

⁹² G Porter n 90.

⁹³ C-36/13 18 December 2014.

⁹⁴ *Ibid* paras 38-39.

⁹⁵ *Open Door and Dublin Well Woman v Ireland* (1993) 15 EHRR 244. *Vo v France* (2005) 40 EHRR 12.

⁹⁶ *Evans v United Kingdom* (2006) 43 EHRR 21.

⁹⁷ *Ibid* 77.

The Convention for Human Rights and Biomedicine (the Oviedo Convention) opened for signature in April 1997 and came into force in December 1999. It is, to date, the only binding international instrument concerning bioethics, biomedicine and human rights. The Convention deals with, amongst other things, patient rights, genetic testing and scientific research. It also permits, under Article 18, research on embryos *in vitro*, provided there is adequate protection of the embryo, but prohibits the creation of embryo for research purposes. At best it is a basic framework on biomedicine from which States are required to implement and enact legislation on the subject matter. It could also be considered a consensus statement on some of these issues. However a deeper examination reveals consensus as to Article 18 to be superficial.

Although the Convention was developed prior to the CAHR, discussions since then have focused on the embryo that may have influence. First the term 'human embryo' is not defined in the Convention and the Working Party on the Protection of the Human Embryo and Foetus agreed that while there is broad agreement across Europe on the need to protect the embryo *in vitro*, consensus on the status of the embryo remains elusive.⁹⁸ This lack of definition is unsurprising when one considers the diversity of approach in Europe. In Spain the term only applies 14 days after fertilisation, while in Germany it applies from the moment of fertilisation.⁹⁹

Second, with the exception of creating embryos for research purposes, it leaves States free to decide whether to permit embryo research, provided there is adequate protection in place. Thus ESCR is not forced upon Member States and the restrictions are limited to the sources of embryos and ensuring there are safeguards to protect the embryo. It echoes the jurisprudence of the ECtHR that largely leaves these issues within the margin of appreciation of Member States. Yet Article 18 has faced criticism from Germany which argue that it is too liberal and contravenes its laws on embryo protection and the UK which has failed to ratify the Convention as it permits the creation of embryos for research.¹⁰⁰ Thus while there is an agreement in place pertaining to embryos *in vitro* any perception of consensus is illusory.

2005-2017: Legislative malaise in Ireland

Within Europe during this period, a tentative consensus emerged: there is recognition that ESCR should occur, but no extra embryos should be created for this purpose. Further, the research should only be conducted when methods such as adult stem cell or iPSC research cannot yield the same results. Although iPSC research is not without its ethical concerns, the research itself is seen as ethically uncontroversial as adult stem cell research and thus encouraged as an alternative to ESCR. On the face of it Brustle does seem out of step with matters of letting Member States decide, but concerns were with commercialisation of the research only and not the research itself. However such consensus is reflective of a restrictive attitude to ESCR and no further agreement on this matter is likely.

In Ireland clarification on the constitutional status of the embryo had in fact little impact. The Supreme Court has definitively stated that an embryo does not fall within the protection of Article 40.3.3 and

⁹⁸ Report by the Working Party on the Protection of the Human Embryo and Fetus, *The Protection of the Human Embryo In Vitro* CDBI-CO-GT3, June 2013, 37.

⁹⁹ V Lúcia Raposo, 'The convention of human rights and biomedicine revisited: Critical assessment' (2016) 20(8) *The International Journal of Human Rights* 1277–1294, 1286.

¹⁰⁰ *Ibid*, 1279–1280.

while declined to pronounce on its status, suggested that it is worthy of respect. In the face of legislative reluctance, both University College Cork (UCD) and Trinity College Dublin (TCD) developed guidelines permitting ESCR.¹⁰¹ Although both policies broadly reflected the recommendations contained in the ICB report, it meant that there was no national conversation on this research and national oversight was lacking. However, despite no legal impediment to ESCR in Ireland, scientists in Ireland continued to be prevented from developing ESCR technology. In the aftermath of the *Roche* decision, the biggest funders of science in Ireland, Science Foundation Ireland and the Health Research Board, announced that on instruction from the Department of Health, no ESCR would be funded as the Department was preparing regulations on assisted reproduction. This moratorium on funding extended to EU funds and, in part due to the complexity of this therapy, large-scale investment from biotechnology companies has been slow to materialise.¹⁰² Thus a *de facto* ban remained in place. This ban has had no impact on IPSC research in Ireland. While researchers cannot use an embryonic control, IPSC research is ongoing.

Brustle also removed a clear financial incentive for biotechnology companies to invest in the research and may have dampened any government enthusiasm to either fund the research or engage in a debate on the status of the embryo. Ireland's Innovation 2020 strategy is seeking to increase Ireland's scientific capacity and infrastructure. Ireland has a growing reputation for adult stem cell research, attracting both national and international funding, and the licensing of therapies from this research has begun.¹⁰³ The development and growth of ESCR in Ireland could complement this growing reputation, but the Innovation 2020 strategy puts a strong focus on securing intellectual property (IP) rights from publically funded research to support innovation.¹⁰⁴ ESCR would therefore fall outside of this strategy. This lack of IP protection came under scrutiny during the discussions of Horizon 2020 when the Legal Affairs Committee of the European Parliament voted against funding ESCR on the grounds that it cannot be patented.¹⁰⁵ The aim of Horizon 2020 is to stimulate European competitiveness and the inability to secure intellectual property rights on the research precludes ESCR from contributing to Europe's competitiveness. Ultimately it was decided to fund ESCR as part of Horizon2020, but *Brustle* may impact future policy initiatives and may have had an impact in Ireland.

Finally, by failing to legislate for the embryo for twelve years, there was an implicit decision to leave it with no protection in law. In stark contrast to the full legal status of the embryo *in vivo*, successive Irish governments have offered the embryo *in vitro* no protection. The status of the embryo depends on its environment alone, a policy that is without a strong moral foundation and has been discussed, potentially contrary to the Constitution. Environment can increase the potential of an embryo to develop into a human being, but it ignores the inherent characteristics of the embryo that contribute to this potentiality. Some of these characteristics (both genetic and moral) can have significant bearing

¹⁰¹ See Trinity College Dublin, *Policy on Good Research Practice* (2009) and University College Cork, *Code of Practice for research Using Embryonic Stem Cell Lines* (2008), available at: <http://www.ucc.ie/en/mandc/news/newsarchive/2008PressReleases/fullstory-63377-en.html> [accessed 13 March 2012].

¹⁰² T Bubela, C McCabe, 'Value Engineered Translation for Regenerative Medicine: Meeting the Needs of Health Systems' (2013) 22(Supp 1) *Stem Cells and Development* 89-93, 89.

¹⁰³ L Siggins, 'Ireland's first stem cell manufacturing centre approved at NUI Galway' 27 January 2014 <http://www.irishtimes.com/news/health/ireland-s-first-stem-cell-manufacturing-centre-approved-at-nui-galway-1.1668830> [accessed 4 January 2017].

¹⁰⁴ Innovation2020 December 2015.

¹⁰⁵ A Abbott, 'Clouds Gather over European Stem-Cell Funding' *Nature News* 26 September 2012.

on the status of the embryo that exist independently of its environment. No decision on the status of the embryo will be free of ethical criticism. Indeed it may not be the inherent characteristics of the embryo, but rather that its representation as the earliest forms of life that is deemed to be morally significant. However legislation on this matter to ensure that the embryo is respected in law, to ensure that researchers can access public funding for ESCR and not leave ESCR solely dictated by a policy on public funds and it is also necessary to have a national dialogue on such matters and not leave them to the privy of local research institutions.

General Scheme of the Assisted Human Reproduction Bill 2017

In October 2017, the General Scheme of the Assisted Human Reproduction Bill 2017 was published and it seeks to regulate assisted reproduction and associated research. Specifically, it makes provisions for gamete and embryo donation for use in assisted human reproduction treatment and research; surrogacy; posthumous assisted reproduction; pre-implantation genetic diagnosis and sex selection; ESCR and IPSC research; and to introduce an independent regulatory authority for AHR.

The Bill is a welcomed development. Years of legislative inaction has prevented embryo research and ESCR from occurring in Ireland. However the Bill as it stands is restrictive in nature, leaves the proposed Regulatory Authority with very limited powers to consider new and emerging developments in this area and, rather unexpectedly, will have an unwarranted and negative impact on IPSC research in Ireland. This Bill as it stands views ESCR as a by-product of assisted reproduction: research is only permitted on those embryos left over after assisted reproduction and fails to consider the wider scientific and ethical justifications for permitting ESCR as an activity in and of itself.¹ *Definition of an embryo*

The first indication of the restrictive nature of the Bill is in Head 2 whereby a human embryo is defined as an entity that is 'formed by the fertilisation of a human egg by a human sperm'.¹⁰⁶ Such a definition is similar to that of the CJEU in *Brustle*, although Irish policy makers were under no obligation to embrace such a definition. *Brustle* pertains to patenting cases only and has no application to the definition of an embryo in the context of research. By adopting such a definition, Irish policy makers have ignored the problems that come with overly prescriptive definitions that are based on fertilisation encountered in other jurisdictions. In the UK, the definition of an embryo under the Human Fertilisation and Embryology (HFE) Act 1990 was originally defined in the context of fertilisation but was later changed to include 'any other process by which the embryo was created began outside the human body'.¹⁰⁷ Such a change came about as a result of a challenge as to whether the HFE Act 1990 encompassed embryos created through somatic cell nuclear transfer (SCNT),¹⁰⁸ and a recommendation that all human embryos, regardless of the mode of creation of the embryo, should fall within the regulations set down by the HFE Act 1990.¹⁰⁹

¹⁰⁶ Head 2, General Scheme of the Assisted Human Reproduction Bill 2017.

¹⁰⁷ S 1(.3) Human Fertilisation and Embryology Act 2008.

¹⁰⁸ Department of Health, *Review of the Human Fertilisation and Embryology Act: Proposals for revised legislation (including the establishment of the Regulatory Authority for Tissue and Embryos)* (2006) para 2.11.

¹⁰⁹ Department of Health, *Review of the Human Fertilisation and Embryology Act: Proposals for revised legislation (including the establishment of the Regulatory Authority for Tissue and Embryos)* (2006) para 2.11.

Embryos created through SCNT are cloned embryos and it is often referred to as ‘therapeutic cloning’ as they are cloned for research purposes and not reproduction.¹¹⁰ A stem cell line created through such as process will be genetically identical to its recipient and likely to be of great benefit in the field of regenerative medicine. Due to the potential benefit of embryos created through SCNT, the CAHR recommended that their use should be permitted for research purposes.¹¹¹ The definition of the embryo as it stands not only restricts the possible sources of a stem cell line, but also leaves the Bill scientifically outdated before it has even become law.

Head 59 and 60 provide an explicit prohibition of the use of embryos through SCNT. Head 59 prevents the creation of embryos for research purposes (and that includes through SCNT) as the availability of spare embryos left over after IVF provides a ready source of embryos and no justification for creation thus exists. Head 60 prohibits the cloning of embryos and a discussion of SCNT is incorporated into that of reproductive cloning, with no distinction made between reproductive and therapeutic cloning.

The prohibition of SCNT is thus problematic on two grounds. First the ethical considerations involved in reproductive cloning are distinct from therapeutic cloning.¹¹² Reproductive cloning is generally perceived to be an affront to human dignity and a threat to human identity. However the purpose of therapeutic cloning is to create a cell line for the treatment of a particular disease or use in a therapy. This brings us to the second issue and that is that there are clear scientific justifications for the creation of embryos for this purpose, arguments the Bill fails to consider or address. 2. *Permitted research*

The value of the Bill is it clarifies the permitted grounds for ESCR: research that can lead to advances in knowledge, treatments or other procedures relating to assisted human reproduction, or the knowledge or treatment of serious diseases or other serious medical conditions is permitted under this Bill.¹¹³ This is almost identical to the funding policies under Horizon 2020 and in compliance with the Oviedo Convention. Importantly for researchers in Ireland, such clarification will enable them to access public funding of research. Importation of stem cell lines is also permitted, provided they only come from spare embryos. This will enable scientists in Ireland to access cell lines from bodies such as the European Human Embryonic Stem Cell Registry, thereby helping to avoid unnecessary creation of embryonic stem cell lines, as required under Horizon2020 guidelines.

The Supreme Court in *Roche* made it clear that the embryo is deserving of respect and consideration must be given as to whether this Bill meets that requirement. The linking of respect with what can be done with the embryo originated in the Warnock Report and has formed the basis of the regulation of IVF and ESCR in the UK and around the world.¹¹⁴ Questions have been asked around whether it is ethically consistent to permit embryos to be used for research while maintaining that they have special respect.¹¹⁵ The answer likely lies in the status afforded to the embryo. If one accepts that the embryo has an intermediate interpretation somewhere between being a clump of cells and having full moral

¹¹⁰ The Ethics Committee of the American Society for Reproductive Medicine, ‘Human Somatic Cell Nuclear Transfer and Cloning’ (2012) 98 *Fertility and Sterility* 804, 804.

¹¹¹ Commission on Assisted Human Reproduction *Report of the Commission on Assisted Human Reproduction* (2005), 62.

¹¹² See J Hansen, ‘Embryonic stem cell production through therapeutic cloning has fewer ethical problems than stem cell harvest from surplus IVF embryos’ (2002) 28 *J Med Ethics* 86–88

¹¹³ Head 63 General Scheme of the Assisted Human Reproduction Bill 2017.

¹¹⁴ Report of the Committee of Inquiry into Human Fertilisation and Embryology 1984 Cmnd 9314.

¹¹⁵ R Isasi, B Knoppers n 5.

status, then some limited form of research is permitted.¹¹⁶ By restricting the use of embryos for research to only the most serious of diseases and having clear oversight of the research, the Bill does satisfy that requirement. The Bill also prohibits the creation of embryos as being currently unwarranted and unjustified due to the availability of embryos left over after IVF. Restricting the creation of embryos for research purposes is thus currently justified on grounds of respecting the embryo provided this supply of embryos remains, although embryos created through SCNT should be an exception to this rule for reasons outlined above.

Head 63 prohibits the development of an embryo beyond day 14 and justifies this on the basis that it 'is a widely established cut-off point because it is the stage at which the primitive streak develops'. However, this stance ignores recent scientific developments in this field in which it may now be possible to develop an embryo beyond day 14.¹¹⁷ It is acknowledged that very little is known about the developmental process of the human embryo from day 14 and that research on these embryos make offer useful insight into congenital defects and improve IVF practices.¹¹⁸ In light of these developments, debates on the extension of this rule have begun elsewhere, but no opportunity for such a debate has been given in this Bill. Once again we may soon see provisions in this Bill quickly becoming outdated.

3. IPSC Research

Arguably the greatest problem with the Bill lies in its restriction of IPSC research as lacking in any legal, ethical or scientific justification and being out of step with international best practice. Head 62(3)(c) states that embryo, ESCR and IPSC research is only permitted where the aims of the research cannot be achieved through alternative forms of research. Head 63(1) puts the same regulatory requirements on IPSC research as ESCR. Thus, researchers who are currently conducting IPSC research in Ireland will now be expected to make an application to the proposed Regulatory Authority to conduct IPSC research, and it must be proven that the research cannot be done by any other means that does not require the use of IPSC research. The justification for introducing such a policy is stated in the Explanatory Notes as being that while 'their source (i.e. adult somatic cells) is not controversial, the potential uses to which they can be put are similar to hESCs'.

As IPSC research is still relatively in its infancy, the development of ESCR in tandem with IPSC research is encouraged. IPSC research is thus not free from any claims of moral complicity. The technology emerged out of ESCR and for now, the technology is very much linked to ESCR and continues to develop within this context.¹¹⁹ However this proposed policy does not make much sense from an ethical standpoint. The purpose of IPSC and ESCR is uncontroversial: it is hoped that it will lead to treatment and cures for the most serious degenerative diseases. It is the source of the cells that goes to the heart of the problem: in the development of ESCR an embryo will be destroyed. It is for this reason that limits are put on the source of cells and parameters of the research. IPSC research, although inadvertently supporting the development of ESCR, is free from the ethical considerations

¹¹⁶ E Parens 'What has the President Asked of NBAC? On the Ethics and Politics of Embryonic Stem Cell Research' in National Bioethics Advisory Commission *Ethical Issues in Human Stem Cell Research* Volume II Commissioned Papers (Maryland, January 2000), 1-7.

¹¹⁷ A Deglincerti, G Croft, L Pietila, M Zernicka-Goetz, E Siggia, A Brivanlou "Self-organization of the *in vitro* attached human embryo" (2016) 53 *Nature* 251-254.

¹¹⁸ S Chan "How to Re-think the 14 day Rule" (2017) *Hastings Centre Report* 5-6.

¹¹⁹ M Brown, 'No ethical bypass of moral status in stem cell debate' (2011) 27(1) *Bioethics* 12-19,, 12-13.

that we see with ESCR and free from the ethical considerations that requires the additional oversight for ESCR that is explicitly stated in this Bill. The source of IPSC research is as ethically unproblematic as adult stem cell research and the aims of IPSC research are laudable. It is for this reason that the International Society for Stem Cell Research has stated that IPSC research does not require the same specialised review as ESCR.¹²⁰ Funding requirements under Horizon2020 similarly do not contain any such requirements for IPSC research. Requiring this extra layer of regulatory approval for IPSC research has no ethical or legal justification and is out of step with international best practice.

4. The Regulatory Authority

Finally, a fundamental problem with this Bill and linked to each of the points above is that it is overly prescribed and gives insufficient power to the proposed Regulatory Authority to regulate these new and emerging technologies. First, despite the clear scientific justification for embryos created through SCNT, it restricts its use and closely links it to reproductive cloning. Second, it restricts the creation of embryos beyond day 14. Third, although a consideration of the ethical and scientific arguments for mitochondrial donation are beyond the scope of this article,¹²¹ both the use of these techniques and research into these techniques are prohibited. This ban is partly justified on the basis of safety concerns and lack of knowledge of the long term impact of such techniques. While such concerns could justify restricting the use of the techniques in humans, it is no basis for a prohibition on research. Appeals to safety for the purposes of research are unwarranted as it is through further research that concerns regarding the safety and long term impact of a new therapy can be resolved.

These restrictions on research are unwarranted and may force patients in Ireland to go abroad for eventual therapies that use such embryos. It also reveals a real lack of confidence in the proposed Regulatory Authority and its associated committees. Under the Bill, approval from a Scientific and Ethics Committee of the Authority will be required before any research can take place. Provided they are appropriately staffed, such committees will be better placed to consider the scientific justifications, safety concerns and the ethical considerations of embryo research than what has been considered in the Bill. Permitting research on embryos beyond day 14 may 'lead to advances in knowledge, treatments or other procedures relating to assisted human reproduction' that cannot be carried out on other embryos. Permitting the creation of embryos through SCNT and mitochondrial research may lead to treatments that cannot come from other sources of embryos. The Bill should be amended to reflect these advances in science, but also acknowledge that the Scientific and Ethics Committee are best placed to consider these issues. Additionally, under Head 63, such licences will only be approved *after* approval from a research ethics committee, thus offering an additional layer of approval. The explanatory notes under Head 70 states that the Regulatory Authority can outline the criteria necessary for the granting of a licence 'as this is likely to be a dynamic process as technology and medical standards change', but the Bill is so restrictive that the Authority will be unable to consider these current, new, and emerging technologies.

¹²⁰ International Association for Stem Cell Research, *Guidelines for Stem Cell Research and Clinical Translation* (2016), para 2.1.

¹²¹ See A Wrigley, S Wilkinson, J Appleby, 'Mitochondrial replacement: ethics and identity' (2015) 29(9) *Bioethics* 631-638. J Appleby, 'The ethical challenges of the clinical introduction of mitochondrial replacement technique' (2015) 18(4) *Medicine, Health Care and Philosophy* 501-514. A Newson, S Wilkinson, 'Ethical and legal issues in mitochondrial transfer' (2016) 8 *EMBO Molecular Medicine* 589-591.

Conclusion

Through the publication of this Bill, Ireland continues to belatedly follow developments elsewhere and refuses to lead on any of these issues. Irish policy makers have also failed to take advantage of the wide ranging debate on many of these issues in other jurisdictions. There are sound scientific justifications for permitting the creation of embryos through SCNT and research on mitochondrial transfer. The requirement of specialised review for IPSC research is not only out of step with international best practise, but defies logic.

In the 12 intervening years since the publication of the CAHR Report, while successive Irish governments have failed to introduce legislation, the Irish courts and the CJEU have been forced to consider some of the issues that go to the heart of embryo research. Almost all countries have regulations that reflect the viewpoint that an embryo has some moral significance.¹²² The General Scheme of the Assisted Human Reproduction Bill 2017 is a welcomed and long overdue development enabling Irish society to consider the complex moral, ethical and legal issues of ESCR. It will bring much needed certainty and the conditions under which embryo and ESCR is permitted are now clear. However it is unduly restrictive in nature, brings new and unnecessary regulation to IPSC research, and perhaps reflects a particular conservative political agenda for ESCR and embryo research, rather than being based on any concern for regenerative research in Ireland. Already the Bill is out of date on some matters and likely soon fall behind international best practice in other areas, necessitating legislative reform should this Bill become law. During the coming months, Irish policy makers must consider these issues and consider the scientific and ethical justification for permitting other forms of ESCR and embryo research. Finally, policy makers must place greater trust in the proposed Regulatory Authority and acknowledge that it will be better placed to oversee this rapidly developing technology.

¹²² S Holm 'Time to reconsider stem cell ethics—the importance of induced pluripotent cells' (2008) 34(2) J Med Ethics 63-64, 63.